

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/	)	
FENFLURAMINE/DEXFENFLURAMINE)	)	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION	)	
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THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	CIVIL ACTION NO. 99-20593
v.	)	
AMERICAN HOME PRODUCTS	)	2:16 MD 1203
CORPORATION	)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8498

Bartle, C.J.

July 1, 2010

Carie Barker ("Ms. Barker" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Dharmendra V. Patel, M.D., F.A.C.C. Based on an echocardiogram dated September 26, 2002, Dr. Patel attested in Part II of Ms. Barker's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$574,011.<sup>3</sup>

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2. (...continued)  
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of  
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In the report of claimant's echocardiogram, Dr. Patel stated that claimant had "[m]oderate [mitral regurgitation]," which he measured as 27.6%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2003, the Trust forwarded the claim for review by David E. Powell, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Powell concluded that there was no reasonable medical basis for Dr. Patel's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only physiologic mitral regurgitation.<sup>4</sup> In support of this conclusion, Dr. Powell explained that "[t]he jet measured on the echo is exclusively confined to very early systole (mitral leaflet closure) and hence does not qualify. Other views, including the parasternal, show only physiologic [mitral regurgitation]."

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3. (...continued)

five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

4. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, physiologic mitral regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5% RJA/LAA."

Based on the auditing cardiologist's finding that claimant had physiologic mitral regurgitation, the Trust issued a post-audit determination denying Ms. Barker's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>5</sup> In contest, claimant submitted an affidavit from Dr. Patel wherein he stated:

I have reviewed the echocardiogram of Carie G. Barker dated 09/26/02 and I conclude that my finding of moderate [mitral regurgitation] based on percentage of [regurgitant] jet area in the left atrium to be accurate in that it was 27% and that correlates with moderate [mitral regurgitation].

Claimant also submitted an echocardiogram report for an echocardiogram performed on March 3, 2003 under the Trust's Screening Program,<sup>6</sup> and prepared by Michael A. Rubin, M.D. In the report, Dr. Rubin noted that claimant had "[m]oderate [mitral regurgitation] with [a] regurgitant jet fraction [of] 34%."<sup>7</sup>

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Barker's claim.

6. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

7. Claimant also contests several purported inconsistencies in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue. First, claimant argued that Dr. Powell responded in Section A that the echocardiogram tape was evaluable  
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The Trust then issued a final post-audit determination, again denying Ms. Barker's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Barker's claim should be paid. On November 30, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4170 (Nov. 30, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 31, 2005. Under the Audit Rules, it is within the Special Master's discretion to

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7. (...continued)  
while he commented in Section H that it was not evaluable. It is true that Dr. Powell responded in Section A that claimant's echocardiogram was evaluable, however, he did not respond in Section H that the echocardiogram was not evaluable. Instead, "Not Evaluable" is merely one choice in a list for the auditing cardiologist to select in completing the form. Here, Dr. Powell selected "Physiologic Regurgitation." Second, claimant suggested that Dr. Powell responded in Section H that claimant's level of mitral regurgitation was physiologic while concluding in Section 2A that claimant did not have mitral regurgitation. Again, claimant misconstrues the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue. Dr. Powell did not respond in Section 2A that claimant had physiologic mitral regurgitation because the only choices are mild, moderate, severe, and none of the above. Notably, in his written explanation to his response in Section 2A, Dr. Powell states that claimant's echocardiogram demonstrated "only physiologic [mitral regurgitation]."

appoint a Technical Advisor<sup>8</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Barker argues, among other things, that in the book Echocardiography, Harvey Feigenbaum, M.D. "states that it does not matter what part of systole the regurgitant jet is noted [for mitral regurgitation] as long as the maximal flow is taken [in] quantifying [mitral regurgitation] ." Claimant also contends that she submitted the March 3, 2003 echocardiogram report "solely for the purpose of showing the consistency of the two tests" regarding her level of mitral regurgitation.

In response, the Trust argues that Dr. Patel's affidavit merely restates his Green Form representations and fails to address Dr. Powell's specific findings at audit. The Trust further contends that claimant's citation to Feigenbaum is misplaced. The Trust also asserts that the jet relied upon by Dr. Patel constituted backflow, not mitral regurgitation and "[n]owhere does Feigenbaum advocate the measurement of backflow to determine a patient's level of mitral regurgitation...." Finally, the Trust asserts that if claimant wanted to rely on her March 3, 2003 echocardiogram to support a claim for Matrix Benefits, then she could have withdrawn her present Green Form and filed a new Green Form based on that echocardiogram prior to audit.

The Technical Advisor, Dr. Vigilante, reviewed claimant's September 26, 2002 echocardiogram and concluded that there was no reasonable medical basis for the attesting

physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante determined that:

The mitral regurgitant jet could easily be found and measured. However, only mild mitral regurgitation was noted.... I made multiple measurements of both the LAA and RJA. I determined that the LAA was greater than 19 [cm<sup>2</sup>]. The left atrial area of 14.6 [cm<sup>2</sup>] calculated by the sonographer on the tape was inaccurate and missed a portion of the left atrium.... Several measurements of the RJA were made by the sonographer on the tape. All of these measurements were less than 3 [cm<sup>2</sup>] except for the last measurement which was calculated at 4.03 [cm<sup>2</sup>]. This measurement is completely inaccurate as the planimetered area contains low velocity non-mitral regurgitant flow. I digitized the same cardiac cycle in which this inaccurate measurement of the RJA was made by the sonographer. The accurate RJA in this cardiac cycle was 3.0 [cm<sup>2</sup>]. Therefore, the accurate RJA/LAA ratio was less than 16% in the cardiac cycle in which the mitral regurgitation appeared the most impressive. The large majority of the other cardiac cycles demonstrated RJA/LAA ratios of less than 10%.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not rebut the specific findings of Dr. Vigilante. She does not challenge Dr. Vigilante's conclusion that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."<sup>9</sup> On this basis

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9. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

Moreover, we disagree with claimant that her attesting physician's affidavit establishes a reasonable medical basis for her claim.<sup>10</sup> As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, both Dr. Powell and Dr. Vigilante found that claimant's attesting physician improperly measured her level of mitral regurgitation. Dr. Vigilante also found that the attesting physician included low-velocity flow in the measurement of claimant's level of mitral regurgitation. Such unacceptable practices cannot provide a reasonable medical basis for the

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10. We also disagree with claimant that the report of her March 3, 2003 echocardiogram provides a reasonable medical basis for Dr. Patel's Green Form representations based on claimant's September 26, 2002 echocardiogram.

resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.<sup>11</sup>

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Barker's claim for Matrix Benefits.

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11. For this reason as well, we reject claimant's argument that the Feigenbaum text provides a reasonable medical basis for Dr. Patel's representation that Ms. Barker had moderate mitral regurgitation.